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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,751

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Naohisa Kawamura

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EXAMINER

WESTERBERG, NISSA M

ART UNIT

PAPER NUMBER

1618

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,751	Applicant(s) KAWAMURA ET AL.	
	Examiner Nissa M. Westerberg	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 5, 7 - 18, 20 - 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of monomers of 2-acetoacetoxyethyl methacrylate and 2-ethylhexylacrylate in the reply filed on June 30, 2008 is acknowledged. The traversal is on the grounds that the species possess unity of invention.

This is not found to be persuasive as polymers of the elected species are known in the art (see below).

Comments and Notes

2. It is noted that the length of the abstract is approximately 250 words. This length exceeds the preferable length of an abstract of 50 – 150 words for an abstract in a National Stage Application (see MPEP 1826 for more information). It is respectfully suggested that Applicant provide an abstract whose length is more consistent with the length guidelines.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 8 – 18 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 8 of copending Application No. 10/585,168. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 8 – 18 and 20 of the instant application are generic to all that is recited in claims 1 – 8 of Application '168. That is, claims 1 – 8 of '168 falls entirely within the scope of claims 8 – 18 and 20 of the instant application or, in other words, claims 8 – 18 and 20 are anticipated by claims 1 – 8 of '168. The claims of '168 recite an adhesive patch (medicinal tape preparation) comprising a support; a pressure sensitive adhesive layer comprising the active ingredient tulobuterol and a acrylic-based pressure sensitive adhesive comprising an acetoacetoxy (meth)acrylate and a vinyl monomer such a 2-ethylhexyl acrylate (see claim 3); and laminated release liner. The claims of the instant application recite a medicinal tape preparation comprising a support, a pressure-sensitive adhesive layer comprising drug and a copolymer comprising a acetoacetyl group containing (meth)acrylic monomer and a monomer such as 2-ethylhexyl acetate (see claim 11 or 12) and a laminated release film.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 8 – 15, 17, 18 and 20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 –

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3, 7 and 8 of copending Application No. 11/792265. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are not patentably distinct. The claims of the instant application recite a medicinal tape preparation comprising a support, a pressure-sensitive adhesive layer comprising drug and a copolymer comprising a acetoacetyl group containing (meth)acrylic monomer and a monomer such as 2-ethyhexyl acetate (see claim 11 or 12) and a laminated release film.

The claims of '265 recite a medical tape preparations with a support, a pressure sensitive adhesive comprising a mixture of polymers and a release liner laminated in that order. One of the polymers in the pressure sensitive adhesive layer comprises a 2-acetoacetoxyethyl methacrylate ester and a vinyl monomer. As exemplified in claim 8, the medical tape preparation can contain a percutaneous absorbable drug.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare the medical tape preparation as described in claim 1 of '265 and to incorporate a drug into the composition, as exemplified in claim 8, arriving at the invention claimed in the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112 2nd Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 1, 2, 7 – 9, 13 – 18 and 20 – 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In these claims it is unclear what possible identities the monomer without the acetoacetyl group can have as “other (meth)acrylic monomers with no acetoacetyl group” is a subset of “copolymerizable vinyl monomers”. The language of the claim seems to indicate that these two items form a Markush group, but the most common Markush group language of “selected from the group consisting of” is not present. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 – 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Knutson et al. (US 5,435,879).

Knutson et al. discloses polymers comprising 1% or 2% acetoacetoethyl methacrylate (AAEMA) and 2-ethylhexyl acrylate (examples 4 and 5, col 17, ln 29 – col 18, ln 7). Polymers comprising these same two monomers are also prepared in examples 9 (col 18) and example 11 (col 18). These composition are normally tacky, pressure sensitive adhesive compositions (abstract) and generally have glass transition temperatures (T_g) of about 0°C, but are preferably about -10°C (Col 7, ln 16 – 32). The test samples are applied to a mylar backing film (col 14, ln 24 – 34) and various physical properties of the adhesive layers determined.

The T_g of the various polymers are not explicitly mentioned in the examples, but given the discussion of desirable T_g in the specification, there is no indication that the prepared polymers do not meet the limitations in the instant claims in regards to T_g. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product

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instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

A recitation of the intended use of the claimed invention ("for a medicinal tape preparation for percutaneous absorption) must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. There is no evidence that the adhesive polymers of Knutson et al. could not be used to prepare a percutaneous absorption medicinal tape.

The polymerization in nonaqueous solvent is a product-by-process limitation. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) **MPEP 2113**. There is no indication that the use of an aqueous solvent will result in a patentably distinct product from a polymer of these monomers produced using a non-aqueous solvent.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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13. Claims 1 – 5, 7 – 18 and 20 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wick (US 4,751,087) in view of Knutson et al. (US 5,435,879).

Wick discloses a pressure-sensitive adhesive tape for delivering the heart medication nitroglycerin to the skin, comprising a flexible backing with a pressure sensitive acrylic adhesive copolymer layer with nitroglycerin (col 2, ln 25 – 56). Isopropyl myristate is a known penetration enhancer for transdermal administration of medicaments (col 1, ln 68 – 69), although Applicant has also identified this compound as a plasticizer. In the third formulation presented in table I (col 9), a total amount of 8.2% of isopropyl myristate is present. The tapes are prepared by mixing the nitroglycerin with the adhesive solution and penetration enhancers (col 6, ln 55 – 66) onto a release liner (col 7, ln 1 – 4). This sheet is dried and laminated onto a backing material using conventional methods (col 7, ln 4 – 6). No water is used in the preparation of the polymers, as shown in example 5 (col 10).

Wick does not disclose the use of an adhesive polymer comprising acetoacetoethyl methacrylate (AAEMA) and 2-ethylhexyl acrylate or the specific temperature at which the polymer is dried.

Knutson et al. discloses polymers comprising 1% or 2% acetoacetoethyl methacrylate (AAEMA) and 2-ethylhexyl acrylate (examples 4 and 5, col 17, ln 29 – col 18, ln 7). The increasing concentration of AAEMA increases the shear strength (table 2). Polymers comprising these same two monomers are also prepared in examples 9 (col 18) and example 11 (col 18). These composition are normally tacky, pressure sensitive adhesive compositions (abstract) and generally have glass transition

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temperatures (T_g) of about 0°C, but are preferably about -10°C (Col 7, ln 16 – 32). The polymers have improved cohesive strength with little or no detrimental effect on tack or adhesion without using a crosslinking monomer (abstract). The test samples are applied to a mylar backing film (col 14, ln 24 – 34) and various physical properties of the adhesive layers determined. These polymers are emulsion polymers so the after application of the mixture to the backing film, the film is dried at 150°C (col 14, ln 30 – 34).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare the drug containing pressure sensitive tape preparation with a laminated structure as taught by Wick and to use the acetoacetoxy methacrylic acid/2-ethylhexyl acrylate pressure sensitive adhesive polymer with improved cohesive strength that doesn't require crosslinking monomers, as taught by Knutson et al.

The T_g of the various polymers are not explicitly mentioned in the examples, but given the discussion of desirable T_g in the specification, there is no indication that the prepared polymers do not meet the limitations in the instant claims in regards to T_g. It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8 a.m. - 4 p.m. ET. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW